



GOVERNMENT OF
NEWFOUNDLAND AND LABRADOR

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LP-11380

Department of
Fisheries and Aquaculture
Office of the Minister

March 31, 2003

FAXED
APRIL 2

Dr. Jennie Butler
Dockets Management Co-ordinator
Center for Food Safety and Applied Nutrition
Docket Management Branch - HFA-305
United States Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland, U.S.A.
20852

Dear Dr. Butler:

Seafood processors in the Province of Newfoundland and Labrador sell a large portion of their production in the United States. As such, my government is concerned about the potential impacts of the draft regulations put forward on February 3, 2003 to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. I ask that you take the following into consideration in making amendments to the draft regulations. My comments reiterate the suggested amendments put forward to you by the Fisheries Council of Canada.

Docket Number: 02N-0276

Title: Section 305, Bioterrorism Preparedness; Registration of Food Facilities.

Under Section S1.227(c)(2) a facility is defined as *"any establishment, structure, or structures, under one management at one general physical location"*.

I am requesting that you change the "one physical location" definition to allow multi-plant operators to register as one firm with one number. Under this one number, the location of each facility would have to be listed.

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Many of the fish companies in this province operate more than one facility. Seafood processors often pack a similar product at several locations. The product is coded for safety purposes, etc. but is often co-mingled in the cold-storage warehouse while awaiting export.

Your draft regulation would require the separation and control in the warehouse of all products by plant registration number and would require carriers to have the new number on both cartons and shipping documents. This will have implications as to the inventory systems and warehousing costs and would add to the complexity of accurately loading container carriers and matching documentation.

Docket Number: 02N-0278

Title: Section 307, Bioterrorism Preparedness; Prior notice of food shipments.

In Section S1.286, prior notice must be submitted no later than noon of the calendar day before the date the article of food arrives at the border crossing.

I ask that you allow for special consideration for live and fresh product and consider two categories of products for prior notice. I propose that your regulations allow shipments of live products to the U.S.A. border to be preceded by a prior notice to FDA of no less than four hours before the shipment arrives at the border point. Fresh perishable or live seafood would not be allowed an amendment to the initial pre-notification information. All other shipments of seafood would be subject to the proposed rule of pre-notification by FDA, before noon of the day preceding arrival at the point of entry. These shipments would be allowed a one-time amendment on volume up to two hours before arrival at the border, under the conditions stated in the regulations.

For fresh product, the four hours notice could still allow for inspection action at the border on these fresh and live products without losses in economic value of the product and risks of spoilage and yields. Many shippers are close to the border and the current draft rules could result in losing a day between loading and notifying FDA and entry into the U.S.A.

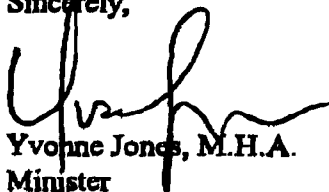
Furthermore, the proposed rule under Section 1.285 would require the prior notice to be submitted by a purchaser or importer who resides or maintains a place of business in the United States acting on behalf of the U.S. purchaser or importer. In practise, most transactions require that the Canadian exporter take responsibility for U.S. Customs and FDA transactions. They remain the owner of the product until delivered to the U.S. customer. The U.S. customer has no direct financial involvement in the shipment until final delivery. As such, it is not reasonable to require them to bear this responsibility. As well, the exporter best knows the contents of each container. The proposed regulation will require the U.S. customer to submit third hand information. I propose that the new regulations should allow the Canadian exporter to submit the prior notice.

3

Also of concern is the proposed rule for originating country. Currently, the draft regulation requires that, other than fish caught by U.S.A. fishers or in U.S.A. waters, the originating country is the country under which the harvesting vessel is flagged. I am suggesting that the standard rules of origin used by U.S.A. customs and the World Trade Organization should continue to be used. Often processors source raw material globally from several countries. Keeping two sets of records for both Customs and FDA prior notice would place undue hardship on firms.

The new regulations will require new systems to be put in place. I, and the industry in my province, understand the importance that the American people have placed on a secure and safe food supply. The proposed modifications will maintain this integrity while, at the same time, they will help ensure the movement of goods between our borders.

Sincerely,



Yvonne Jones, M.H.A.
Minister

pc. Alastair O'Rielly, FANL



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Comments:

Michelle:

As the letter was mailed yesterday, the Dockets Management Co-ordinator title is shown, as was given to me by a person named Alberta at the United States Food and Drug Administration. Please advise if you received this fax either by phone or fax.

Thank you for your assistance.

Lynette